TRIUMVIRATE
ENVIRONMENTAL

10/27/2022

Lisa Golden
Director, Lowell Health and Human Services
107 Merrimack St 4th Floor
Lowell, MA 01851

Francesca Cigliano
Interim Director, Development Services
375 Merrimack St
Lowell, MA 01852

Re: OncoFiltration Applicability for Lowell Board of Health rDNA Permit

To Ms. Golden, Ms. Cigliano, and to whom it may concern:

OncoFiltration is a biotechnology company specializing in the development of a propriety system to filter our circulating tumor cells from whole blood. As a part of the research and development for this therapeutic filtration and diagnostic testing, OncoFiltration utilizes polymerase chain reactions (PCR) on extracted, genomic nucleic acids from whole blood and established (non-recombinant) human cancer cell lines for identification and screening purposes. This PCR involves the use of PCR primers that are small, synthetic oligonucleotides, typically 18-to-30 nucleotides long.

The National Institutes of Health's (NIH) Office of Science Policy regulates use of recombinant and synthetic nucleic acids for all institutions funded by the NIH through a guidance document called the *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules* (NIH Guidelines). Many Massachusetts local jurisdictions require compliance with the NIH Guidelines for institutions that do not receive NIH funding by enacting local rDNA permitting requirements, including the City of Lowell.

The use of synthetic PCR primers falls under Section III-F of the NIH Guidelines, specifically subsections 1, 2, and 6. This section of the NIH Guidelines is explicitly a group of experiments that are considered low risk and are accordingly exempt from standard review requirements by the local Institutional Biosafety Committee as the guidelines are written.

The City of Lowell Code, Ch. 10, Art. V of the 1988 Code, Part II, Article III defines "Recombinant DNA Molecules (rDNA)" as:

> Deoxyribonucleic acid molecules which are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell or DNA molecules which result from the replication of rDNA molecules.

I write this letter to ask for an official determine whether OncoFiltration's use of synthetic PCR primers falls within the scope of requiring an rDNA permit from the City of Lowell. These nucleic acids in use are synthetic only, not joined to any natural DNA segments or molecules, do not possess a prokaryotic or eukaryotic origin of replication, and are not modified in any way in which they could enter a cell.

Please do not hesitate to contact me if you have any questions about this determination or OncoFiltration's work.

Sincerely,

Brandon Linz, PhD, RBP (ABSA)
EHS Director of Biosafety
Triumvirate Environmental, Inc.
200 Inner Belt Rd
Somerville, MA 02143

Cc:
Abiche Dewilde, PhD, Vice President of Research, OncoFiltration
Karen Yip, MPH, EHS Consultant, Triumvirate Environmental
Tyler Kosiba, EHS Consultant, Triumvirate Environmental